REMARKS

Claims 1 – 4, 6 – 14 and 17 - 24 are pending in the application. Claims 1, 8 – 11, and 24 have been amended. Claims 3, 5 – 7, 12, 15 and 16 have been cancelled. No new claims have been added. No new matter has been added by virtue of the amendments and claims, support being found throughout the specification and claims as originally filed.

Any cancellation of the claims should in no way be construed as acquiescence to any of the Examiner's rejections and was done solely to expedite the prosecution of the application. Applicant reserves the right to pursue the claims as originally filed in this or a separate application(s).

Claim Rejections

35 USC 112, First Paragraph

The Examiner has rejected claims 1 – 4, 6 – 14, 17 and 24 under 35 USC 112, first paragraph. The Examiner argues that the specification, while being enabling for diagnosing pancreatic cancer by detecting a methylated SPARC nucleic acid molecule which SPARC nucleic acid molecule comprises the nucleic acid sequence set forth in SEQ ID NO: 1, does not reasonably provide enablement for all cancers or possible variants thereof." (Office Action, p.2) Applicants respectfully traverse the rejection.

While in no way acquiescing to any validity of the Examiner's rejection, and solely in the interest of expediting prosecution, Applicants have amended the claims to recite that the cancer is pancreatic cancer.

Accordingly, Applicants respectfully request that the rejection be withdrawn.

35 USC 102(a)

The Examiner has rejected claims 1 – 3, 6 – 8, 13 – 14 and 17 under 35 USC 102(a) as being anticipated by Shuber (US 2003/0087258). Applicants respectfully traverse the rejection.

Instant claim 1 recites a method for diagnosing pancreatic cancer, comprising the detection of a methylated SPARC nucleic acid molecule or a variant thereof in a sample from a subject, wherein the methylated SPARC nucleic acid molecule has at least about 90% sequence identity to a the nucleic acid set forth in SEQ ID NO: 1 (Figure 6).

To anticipate a claim, each and every element of the claim must be found in a single reference. This is discussed in the Manual of Patent Examining Procedure § 2131:

> "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the . . . claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an ipsissimis verbis test, i.e., identity of terminology is not required. In re Bond, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

The Shuber reference does not teach or suggest all the limitations of the instant claims. In particular, the Shuber reference does not teach or suggest a method for diagnosing **pancreatic cancer**, comprising the detection of a **methylated SPARC nucleic acid** molecule or a variant thereof in a sample from a subject, **wherein the methylated SPARC nucleic acid molecule has at least about 90% sequence identity to a molecule identified in SEQ ID NO: 1 (Figure 6)**.

The Examiner argues that "Shuber teach a method of diagnosing cancer (i.e. colorectal cancer) in humans by detecting aberrant methylation in regulatory region of the H1C1 gene, p14 gene, the HLTF gene, the MINT gene and/or the MINT31 gene, and of which could be termed a variant of the SPARC gene comprising SEQ ID NO: 1." (Office Action, p.4).

Nowhere does the Shuber reference, expressly or inherently, teach or describe a method comprising the detection of a methylated SPARC nucleic acid molecule or a variant thereof in a sample from a subject in a detection method for pancreatic cancer. Further, none of the H1C1 gene, p14 gene, the HLTF gene, the MINT gene and/or the MINT31 genes share at least about 90% sequence identity to the nucleic acid set forth in SEQ ID NO: 1 (Figure 6).

Based on the foregoing; Applicants submit that the claims are not anticipated by the Shuber reference.

Accordingly, Applicants respectfully request withdrawal of the rejection and allowance of the claims.

35 USC 103(a)

The Examiner has rejected claims 4, 9 – 12 and 18 - 24 under 35 USC 103(a) as being unpatentable over Shuber (as above) as applied to claims 1 – 3 and 6 – 8, and further in view of Sato et al. (Onceogene 22:5021 – 5030). (Office Action, p.6). Applicants respectfully disagree.

Claim 4 depends from claim 1 and recites that the sample is obtained from a mammal suspected of having a pancreatic cancer.

The present Application is a National Stage filing of patent Application US04/020535, filed 6/24/04, that claims priority under 35 USC 119(e) to 60/482,146, filed 6/24/03.

The Sato et al. reference, published in Issue 32 (7 August 2003). Accordingly, the Sato et al. reference cannot be properly applied in the foregoing rejection.

Applicants respectfully request that the rejection be withdrawn.

CONCLUSION

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

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Respectfully submitted,

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